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# NUCLEAR REGULATORY COMMISSION

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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VIDEO-TELECONFERENCE

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WEDNESDAY,

DECEMBER 15, 2021

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The meeting was convened via Video-Teleconference, at 2:00 p.m. EST, Darlene F. Metter, ACMUI Chairman, presiding.

MEMBERS PRESENT:

DARLENE F. METTER, M.D., Chairman

VASKEN DILSIZIAN, M.D., Vice Chairman

REBECCA ALLEN, Member

RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

HOSSEIN JADVAR, Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

MICHAEL D. O'HARA, Ph.D., Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

CHRISTIAN EINBERG, Designated Federal Officer

MARYANN AYOADE, NMSS/MSST/MSEB

ANGELA COGGINS, OGC/LHE/MFW

DANIEL DIMARCO, NMSS/MSST/MSEB

ROBIN ELLIOTT, R-I/DRSS/MLB

CINDY FLANNERY, NMSS/MSST/SLPB

VINCENT HOLAHAN, NMSS/MSST

DONNA-BETH HOWE, Ph.D., NMSS/MSST/MSEB/MRST

IAN IRVIN, OGC/GCRPS/RMR

ERIN KENNEDY, R-III/DNMS/MLB

PENNY LANZISERA, R-I/DRSS/MLAB

SARAH LOPAS, NMSS/MSST/MSEB

DONALD LOWMAN, NMSS/MSST/MSEB

JOAN OLMSTEAD, OGC/LRAA/RASFP

VERED SHAFFER, RES/DSA/RPB

KATHERINE TAPP, Ph.D., NMSS/MSST/MSEB

ELIZABETH TINDLE-ENGELMAN, R-III/DNMS/MIB

JOHN TOMON, RES/DSA/RPB

CELIMAR VALENTIN-RODRIGUEZ, Ph.D., NMSS/MSST

KEVIN WILLIAMS, NMSS/MSST

ALSO PRESENT:

MICHAEL SHEETZ, University of Pittsburgh School of Medicine

P R O C E E D I N G S

AGENDA

P R O C E E D I N G S

2:02 p.m.

MR. EINBERG: Good afternoon. As the Designated Federal Officer for this meeting, I am pleased to welcome you to this public teleconference meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Chris Einberg. I am the Chief of the Medical Safety and Events Assessment Branch and have been designed as the federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. This meeting is being transcribed by the NRC and it may also be transcribed or recorded by others. The meeting was announced in the December 1, 2021 edition of the Federal Register, Volume 86, page 68289.

The purpose of this teleconference meeting is to discuss the ACMUI Subcommittee on Alpha DaRT's review and comments on the NRC staff's draft licensing guidance on the Alpha Tau Alpha DaRT Manual Brachytherapy, to discuss the ACMUI Subcommittee on

Reg Guide 8.39's review and comments on the NRC staff's draft additional considerations memorandum for CivaDerm Superficial Manual Brachytherapy, and to discuss the ACMUI Subcommittee on Reg Guide 8.39's review and comments on the NRC's draft revision of Regulatory Guide 8.39 Release of Patients Administered Radioactive Material.

The function of the ACMUI is to advise the staff on issues and questions that arise on the medical use of byproduct material. The committee provides counsel for the staff, but does not determine or direct the actual decisions of the staff or the commission. The NRC solicits the views of the committee and values their opinions.

I request that, whenever possible, we try to reach consensus on the various issues that we will discuss today, but I also recognize there may be minority dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point, I would like to perform a roll call of the ACMUI members participating today. Dr. Darlene Metter, Chairman and Diagnostic Radiologist?

CHAIR METTER: Present.

MR. EINBERG: Dr. Vasken Dilsizian, Vice Chairman and Nuclear Cardiologist?

VICE CHAIR DILSIZIAN: Present.

MR. EINBERG: Dr. Ronald Ennis, Radiation Oncologist?

MEMBER ENNIS: Present.

MR. EINBERG: Mr. Richard Green, Nuclear Pharmacist?

MEMBER GREEN: Present.

MR. EINBERG: Dr. Hossein Jadvar, Nuclear Medicine Physician?

MEMBER JADVAR: Present.

MR. EINBERG: Mr. Josh Mailman, Patients Rights Advocate?

MEMBER MAILMAN: Present.

MR. EINBERG: Ms. Melissa Martin, Nuclear Medicine Physicist?

MEMBER MARTIN: Present.

MR. EINBERG: Dr. Michael O'Hara, FDA Representative?

MEMBER O'HARA: Present.

MR. EINBERG: Mr. Zoubir Ouhib, Radiation Therapy Physicist, is not able to attend today. Ms. Megan Shober, State Government Representative? Megan, are you on the line?

MEMBER SHOBER: Can you hear me?

MR. EINBERG: Yes, we can hear you, but not very loud, but we can hear you. Dr. Harvey Wolkov, Radiation Oncologist?

MEMBER WOLKOV: Present.

MR. EINBERG: And Ms. Rebecca Allen, Healthcare Administrator?

MEMBER ALLEN: Present.

MR. EINBERG: We also have Mr. Michael Sheetz participating as a non-voting member as a medical consultant. Mr. Sheetz, are you present?

MR. SHEETZ: Yes, I am present.

MR. EINBERG: And is Dr. John Angle also present and participating as a non-voting medical consultant?

MS. LOPAS: Chris, I am looking for him. I might not have -- I don't see him in the participants list. Dr. Angle, if you called in on your phone, press star, five, and that will raise your hand and I'll be able to enable your phone microphone.

MR. EINBERG: Okay, thank you, Sarah. I do confirm that we do have a quorum of at least six members.

All members of the ACMUI are subject to

federal ethics laws and regulations and receive annual training on these requirements.

If a member believes that he or she may have a conflict of interest as that term is broadly used within 5 CFR Part 2635 with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and to the Designated Federal Official as soon as possible before the ACMUI discusses it as an agenda item.

ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest unless they've received a waiver or prior authorization from the appropriate NRC official.

The NRC commenced reentry on November 7. The NRC is operating in a hybrid work environment with NRC staff members coming into the office at least two days a week.

NRC staff members who are participating in this meeting today include Ms. Sarah Lopas, Mr. Don Lowman, Mr. Daniel Dimarco, Dr. Katie Tapp, Dr. Donna-Beth Howe, Ms. Cindy Flannery, Ms. Maryann Ayoade, who will be joining us a little bit later, and Dr. Celimar Valentin-Rodriguez will also be joining us a little bit later.

Members of the public who notified Mr. Lowman that they would be participating on the teleconference will be captured as participants in the transcript.

Those of you who did not provide prior notification, please contact Mr. Lowman by email at donald.lowman, D-O-N-A-L-D dot Lowman, L-O-W-M-A-N, @nrc.gov at the conclusion of this meeting.

Today's meeting is being transcribed by a court reporter. We are utilizing Microsoft Teams for the audio of today's meeting and to view presentation material in real time. The meeting materials and the agenda for this meeting can be accessed by the NRC's public meeting schedule site.

Dr. Metter, at her discretion, may entertain comments or questions from members of the public who are participating today.

Individuals who would like to ask a question or make a comment regarding the specific topic the committee has discussed should please use the raise hand function in Microsoft Teams to signal to our Microsoft Teams host, Sarah Lopas, that you wish to speak.

If you have called into the Microsoft Teams using your phone, please press star, five to

raise your hand. When you begin your comment, please clearly state your first and last name for the record.

Comments and questions are typically addressed by the committee near the end of the presentation after the committee has fully discussed the topic.

We will announce when we are ready for the public comment portion of the meeting and an NRC staff member will assist in facilitating public comments.

At this time, I ask that everyone who is not speaking to please mute your Teams microphones or mute your phones. I would also ask that everyone exercise extreme care to ensure that the background noise is kept to a minimum as any stray background sounds can be very disruptive on a conference call this large.

At this point, I'd like to turn it back to Dr. Metter. Dr. Metter?

CHAIR METTER: Thank you, Mr. Einberg, for your excellent opening. At this point in time, our next agenda item will be the draft report review by the ACMUI Alpha DaRT Licensing Guidance Subcommittee on the draft report on the NRC staff draft licensing guidance, and for this, Dr. Ronald

Ennis will be presenting the subcommittee report. Dr. Ennis?

MEMBER ENNIS: Thank you, Dr. Metter, and hello, everyone. Thank you for joining today. It's my honor to present on behalf of the subcommittee commenting on the draft guidance of the NRC staff on the Alpha Tau Alpha DaRT Manual Brachytherapy source. Next slide, please.

This is a list of our subcommittee members. We have an excellent subcommittee, many active participants, and including Mr. Sheetz, and Dr. Katie Tapp was our NRC resource. Next slide.

So, as stated, our charge was to comment on the draft licensing guidance for this brachytherapy source that has been drafted by NRC staff. Next slide.

The first and maybe most important decision the NRC faced was where it should be, this isotope should be categorized, and they have decided to license it under 35.1000. Our subcommittee agrees with that decision.

This isotope is unique and has some elements of a brachytherapy source, but some of a radiopharmaceutical source in that the radioactive material is adherent to the surface of the device

rather than a sealed source, and the daughter particles or elements diffuse through tissue and go on to go further decay so that it is permeating through the body, somewhat akin to radiopharmaceuticals.

So, it makes a lot of sense to us as well to license this under 35.1000 but drawing on some of the principals from 35.300 and 400 for radiopharmaceuticals and sealed source brachytherapy respectively. Next slide.

Now getting into some specific comments, there are a number of specific comments over the next several slides that we will comment on. First, in terms of the role of the authorized medical physicist.

The subcommittee does not believe that acceptance testing of treatment planning software requires an authorized medical physicist but rather should be done by a qualified medical physicist.

In addition, we do not believe that the authorized medical physicist is the appropriate person to provide training for the radiation safety officer regarding this source.

Rather, the training should come from either the vendor or from a radiation safety officer

who has previously been trained in this source. Next slide. Next slide, please.

MS. LOPAS: Did it go through for you?

MEMBER ENNIS: No.

MS. LOPAS: Okay, let me -- it moved forward for me, so hang on. Let me know when you see it. It's the role of the nuclear pharmacist, correct?

MEMBER ENNIS: Yes.

MS. LOPAS: Got it.

MEMBER ENNIS: Yes, thank you. Okay, so in terms of the role of nuclear pharmacist, the subcommittee does not see any role for a nuclear pharmacist.

This is not a drug in any sense, so there's no pill. There's no fluids that would be processed by a pharmacist. It's a brachytherapy source with a radioactive radium adherent to its surface. Next slide. It did not advance.

MS. LOPAS: All right, I'm going to disable incoming video and maybe that will help with my bandwidth as well. All right, just let me know, Dr. Ennis, when it does advance, because it's advanced on my side.

MEMBER ENNIS: Oh, okay, good.

MS. LOPAS: Sorry, it's a very slow

delay. I apologize.

MEMBER ENNIS: All right, as long as the audience can be patient, I'm okay. All right, so in terms of assessment of leakage, so there was a few comments on this topic as well.

The subcommittee does not believe there's a role for assessment of patient surface contamination or leakage. The radioactive particles are going to be diffusing through tissue in all directions, including towards the body surface, so a source placed close to the surface will, of course, have radioactive radioactivity emanating from it and be detectable on the surface and there's no way to differentiate that from a spill, if you will. It's not really something that would spill, so we don't believe that concept really applies for this source.

Right, and similarly, leak testing of the source also is not applicable because, again, it is not a sealed source, but rather the radioactive radium is adherent to the surface. Next slide.

Okay, and in a similar vein, there doesn't seem to be an appropriate need to check for the source seal in that it would not affect dose delivery should the seal be broken. Next slide.

However, because this particle is

adherent to the surface, if the source were to come into contact with any surfaces in the procedure room, there could be a possibility of contamination to those surfaces, so that needs to be addressed, and therefore, we would recommend that following the typical standard contamination guidance that already exists in NUREG 1556 Volume 9 be followed in such a situation for this applicator as well.

And a very minor point, but rather than say survey instrument used, we'd prefer radiation detection instrument used, which is a bit more generic term. A survey has a certain connotation of possibly a specific instrument for some people. Next slide.

In terms of patient release, just some wordsmithing if you will, but possibly with some importance.

We recommend changing the language of the requirement that the patient should not be released from what is currently stated as if it is possible under normal circumstances for a seed or a seal to become dislodged and change that to likely under normal circumstances.

Basically, anything is possible, whereas a better assessment of whether it was reasonable to

discharge the patient is whether it was likely to have been able to be predicted by the authorized user. Next slide.

Okay, in terms of medical event, the subcommittee agrees with the proposed definition of medical event for temporary implants, which is the current FDA clearance for this applicator.

However, if the manufacturer were to obtain approval for permanent implantation, then the subcommittee would recommend that the definition for medical event be the same as for other permanent brachytherapy applications.

As many on this call are well aware, that was the subject of significant debate for a long period of time and modifications to the rule were made a couple of years ago that have had a positive effect, and those principles would apply to other permanent brachytherapy as well.

So, if this source is licensed eventually under for permanent brachytherapy use, the medical event definition needs to follow that.

So, as an aside, the draft guidance does state that even if the source is later authorized by FDA for permanent use, there is not an expectation by the authors of the guidance to need to make revisions.

So, that if that is the case, then we would recommend adding a definition for medical event and the setting of permanent implantation to the current licensing so that when that eventuality does occur, there indeed is no need for NRC to reissue the guidance. Next slide.

There is a suggestion in the licensing guidelines that there be a documentation of the locations a patient is likely to be. The subcommittee does not believe this documentation of where the patient anticipates to spend significant time would really add any safety benefit. We do not support, therefore, this documentation requirement without any clear use for it. Next slide.

CHAIR METTER: Thank you, Dr. Ennis, for your presentation. Now I'd like to turn it over to Sarah Lopas to entertain any questions for the report by either the ACMUI, staff and then followed by that of the public. Ms. Lopas?

MS. LOPAS: Thank you, Dr. Metter. So, to make a comment, we would ask that you all press -- use the hand icon. So, just click on the hand icon if you're using Teams.

If you're on the phone and you would like to make a comment, you're just going to press star,

five on your phone and that's going to raise your hand.

So, I have to enable your microphone, so that's what's going on here. So, I'll just keep an eye out for any raised hands. So, press star, five if you're on the phone or press the hand icon if you're using the Teams interface here on our computer or on your cell phone if you have logged into Teams on your cell phone.

MR. EINBERG: Just -- and this is Chris Einberg. Just a point of clarification, Dr. Metter and Sarah.

MS. LOPAS: Okay.

MR. EINBERG: The ACMUI is discussing comments first and then it will go the public.

MS. LOPAS: Okay, all right, we'll take that back. Let's hold off on comments, but now you know how to do it. So, Dr. Metter, I'll send it back to you to lead the conversation with the ACMUI.

CHAIR METTER: Yes, thank you, and thank you, Chris, for that clarification. Are there any comments by the ACMUI members on Dr. Ennis' draft report on the Alpha DaRT manual brachytherapy licensing guidance?

(Pause.)

MS. LOPAS: And ACMUI folks, you'll just have to remember to unmute yourselves if you're trying to speak.

CHAIR METTER: I'm not seeing any hands raised or any comments.

MS. LOPAS: I am not seeing any either, Dr. Metter.

CHAIR METTER: Okay, thank you. I'd like to also entertain if there are any NRC staff that would like to make comments on the subcommittee report?

(No response.)

CHAIR METTER: Okay, I'm also not seeing any hands raised or anybody making comments on this. So, do you see that too, Ms. Lopas?

MS. LOPAS: Correct, I'm not seeing any hands raised.

CHAIR METTER: Okay, so now we'll go ahead and turn it over to public comments.

MS. LOPAS: Okay.

CHAIR METTER: I'll let you take that, Ms. Lopas.

MS. LOPAS: Yes.

CHAIR METTER: Thank you.

MS. LOPAS: Yes, so I'm back opening up

the public comments. So, as I said, use the hand icon to make a comment and I will enable your microphone, and then you will have to unmute yourself, all right? I see Ralph. Ralph, I'm going to go ahead and allow your microphone and now you just unmute yourself, Ralph, and you'll be able to speak.

MR. LIETO: Hi, is it working?

MS. LOPAS: It is. We can hear you.

MR. LIETO: Okay, thank you, and thank you for the opportunity to ask questions. I just really have two questions of clarification, one for the committee and one for NRC staff.

For NRC staff, regarding this report, when you say it's a draft, does it mean that after the comments, and assuming it's all accepted by the ACMUI, does this report or guidance go out for draft or for comment by the public or is this the only time where the public is going to be able to comment on revisions?

MS. LOPAS: Chris, I'm wondering if that's a process type question, or Katie, yeah, why don't you go ahead and answer that one? Great, thank you, Dr. Tapp.

DR. TAPP: Sure, this is Katie Tapp. So,

for licensing guidances, when they first come out, they will, we'll take the ACMUI comments and then we will go through our concurrence and management review, legal review, and issue them without public comment.

That being said, in this case, it is likely we will send it to the manufacturer to make sure, to get any comments from them, as well as this is such an early guidance, early in the use of this product in the United States, so we will continue to keep an eye on the product and the uses.

And we'll gather information as it starts to be used more and we can update it if necessary, if we find something that needs to be changed or a new safety hazard that wasn't evaluated during the research protocols. If we find something new, it can be updated at that time.

So, as it goes out and is being used in this research time, we can receive comments from the users, from the manufacturers, and from the public, and update it as necessary.

MR. LIETO: So, there would not be -- so I'm gathering what you're saying is that yes, the public can comment now, and there's not necessarily a deadline for comments, but I would assume that you

would want them probably sooner than the manufacturer completing their assessment?

DR. TAPP: Yes, if you have some comments on the draft report, you can send them to us, as well as we can take them later, but if you get them in before it's used first, that would be something we would look at.

MR. LIETO: Approximately how long would that be?

DR. TAPP: It's always hard to tell. We do expect to have it published by late winter --

MR. LIETO: Okay, all right.

DR. TAPP: -- assuming there's no other --

MR. LIETO: So, if you get it like in the next 30, 60 days, that would be --

DR. TAPP: Yes.

MR. LIETO: -- reasonable?

DR. TAPP: Yes.

MR. LIETO: Okay.

DR. TAPP: But we do not expect it to need a public comment period.

MR. LIETO: Okay, okay.

DR. TAPP: Thank you.

MR. LIETO: And my other question for the

committee was just I had a little misunderstanding or I'm not sure if I understood the medical event recommendation, and if they could maybe just clarify that, I'd appreciate that.

MEMBER ENNIS: Sure, so the medical event definition in permanent brachytherapy, it was found that a dose-based definition could, did result in a substantial number of medical events that were really not genuinely medical events just because of the high sensitivity of the dose distribution with slight variations in seed placements that is inherent in a permanent placement.

And without an ability to control the dwell time because it's permanent, there's no way to adjust for that as opposed to temporary brachytherapy. We can always adjust the dwell times.

So, an activity-based definition was adopted such that the activity has to be implanted in the organ or the target site as prescribed, as planned beforehand, and a medical event is assessed on that basis.

And that, you know, had been working well in the permanent brachytherapy space, and would be the recommendation if this were used for permanent applications for the same reasons.

MS. LOPAS: All right, thank you, Dr. Ennis. Hey, Dr. Donna-Beth Howe, I see you have your hand raised. Go ahead.

DR. HOWE: Yeah, this is just a clarification that when we issue guidance for 35.1000 uses, that unlike other guidance documents, it's always considered open and we always can receive new comments on it.

We may not revise the guidance right away to address new comments, but we keep track of them, and when we think that it's time to revise the guidance, we will.

So, there is no set comment period. You need to get your comments in early for the first guidance document, but once the document is posted, NRC receives comments at any time. Thank you.

MS. LOPAS: All right, thank you, Dr. Howe. So, press the hand icon if you have a comment for the ACMUI, and if you're on your cell phone if you called into today's meeting, you'll just press star, five, and we'll give it one last call for this presentation on Alpha DaRT.

And then, Chris, after Alpha DaRT, would we then just move onto the next presentation? Is that correct?

MR. EINBERG: No, then there should be a motion to adopt the report, and then if the committee that votes on it and then adopts it, the full report, and then --

MS. LOPAS: Right.

MR. EINBERG: -- it becomes a committee report.

MS. LOPAS: Okay, great, thank you. All right, I'm just giving it another scan. I see no hands raised, so I think, Dr. Metter, we can move forward.

CHAIR METTER: Thank you, Sarah, for entertaining those questions and comments. So, at this point in time, as Chris had mentioned, I would like a motion to approve the subcommittee report on the Alpha DaRT licensing guidance. Do I have a motion to approve the report?

MEMBER JADVAR: Motion to approve, Hossein Jadvar.

CHAIR METTER: Thank you, Doctor.

MEMBER WOLKOV: Harvey Wolkov, second.

CHAIR METTER: Thank you, Dr. Wolkov, second. Any discussion? Okay, all in favor, say aye.

(Chorus of aye.)

CHAIR METTER: Any opposed or abstained?

Hearing none, the subcommittee report is unanimously approved by the ACMUI.

So, our next presentation is by Ms. Megan Shober, our agreement state representative, who will present the ACMUI subcommittee report on the CivaDerm draft report on the NRC staff's additional consideration memo for CivaDerm, and she'll comment on the licensing guidance for this CivaDerm. Ms. Shober?

MEMBER SHOBER: Thank you. I did switch my microphone. I just want to make sure that you can hear this one better?

MS. LOPAS: Yeah, we can. You sound great, Megan. Thank you.

MEMBER SHOBER: Okay, all right. Okay, so a couple of months ago, Dr. Metter charged the Reg Guide 8.39 Subcommittee to review the draft CivaDerm licensing guidance with regard to patient release. So, next slide, please.

These are the subcommittee members. Again, this is the same subcommittee as was evaluating Reg Guide 8.39. Katie Tapp served as the NRC staff resource for the CivaDerm guidance as well. Next slide, please.

And our charge, as I mentioned, was to review this draft licensing guidance specifically with regard to patient release in line with the draft revision to the Reg Guide 8.39. Next slide, please.

So, CivaTech Oncology has the CivaDerm manual brachytherapy device. It contains sealed palladium-103 sources, and it's FDA approved for use as intraoperative or superficial temporary brachytherapy source to treat skin cancer or other lesions. The primary intended use is superficial application.

So, NRC did evaluate this product and has determined that the use of CivaDerm will be licensed under 10 CFR 35.400, which is manual brachytherapy, because radiation protection concerns for this device are adequately covered under existing regulations in 10 CFR 35 Subpart F.

However, NRC staff determined that additional guidance may be needed regarding patient release because the sources have the potential to become dislodged during the treatment.

NRC did add a relevant section in the Draft Regulatory Guide 8.39 but is expecting that reg guide to take some time to finalize, and since CivaDerm is already approved by the FDA, NRC decided

to prepare separate guidance for CivaDerm at this time. Next slide.

So, within the subcommittee, we really had a couple of questions that we wanted to focus on. The first one is again NRC identified that this CivaDerm product has, the sources have the potential to become dislodged. So, within the subcommittee, we discussed what is the potential for the sources to become dislodged?

And then following up on that, does an increased risk of dislodgement warrant additional patient release considerations? So, those were really the two core questions that the subcommittee looked at. Next slide, please.

So, after discussions, we do have a number of recommendations. The subcommittee agrees that CivaDerm should be licensed under 10 CFR 35.400. We agree with NRC that the radiation safety issues that are presented are already covered by 10 CFR 35 Subpart F.

And then we, as the subcommittee, also recommended developing much shorter guidance that focuses on the consequences of loose or dislodged sources.

Because CivaDerm can be regulated under

10 CFR 35 Subpart F, the regulations are already all there, so any guidance the NRC wants to put out should be very focused on the specific concern of this particular product, in this case, the loose or dislodged sources. Next slide, please.

As the subcommittee, we do believe that it's highly unlikely for public dose limits to be exceeded even if a dislodged palladium-103 source is able to expose bystanders to radiation.

Part of the reason for that is because palladium-103 does have a very low energy gamma, so the gamma does not travel very far, and the public dose limits are based on effective dose equivalent, 100 millirem effective dose equivalent, and with a low-energy gamma emitter, it's very difficult to have a whole body exposure with the low-energy gamma.

So, the subcommittee does believe that it would be very difficult to exceed a public dose limit from a source that is dislodged from the CivaDerm application. Next slide, please.

The subcommittee also believes that other temporary brachytherapy sources have similar risks of becoming loose or dislodged. The most similar type of therapy would be with an eye plaque, I-125 eye plaque, so the risks that CivaDerm presents are not

brand-new.

The regulating community has been working with these types of risks for a long time and we haven't seen, for example, eye plaque seeds that have come out from applicators very often. It's not a common problem.

And then again, just we, the subcommittee feels that the guidance that NRC put out for lutetium-177 is a much better model in terms of what this draft guidance should look like. It's very concise. It focuses on the specific issue at hand, so we did make a number of editorial recommendations to bring it in line with that type of format. Next slide.

And that completes the presentation. Thank you.

CHAIR METTER: Thank you, Ms. Shober, for your thorough report by your subcommittee on this new product. Are there any questions from the ACMUI for Ms. Shober? Okay, seeing none, any questions from the NRC staff? Also seeing none, I now turn it over to Ms. Lopas who will now address any comments from the public. Thank you.

MS. LOPAS: So again, use the hand icon up at the top of your Teams screen if you'd like to make a comment for the ACMUI and NRC staff's

consideration, or you press star, five if you used your phone to call in, and I'll keep an eye out for any raised hands.

And I just wanted to check in with Mr. Mailman. You're able to enable your microphone, correct, Mr. Mailman? I saw that you were disabled temporarily. Josh, are you -- I just wanted to check in on your audio. Are you good, Josh?

Okay, I see a hand raised. All right, Josh, you should be able to unmute yourself. Your microphone is enabled, so, unless you're maybe having Teams issues, and if you're having Teams issues, I can email you quickly or you could try to call in with your cell phone and maybe you could just send me your -- and raise your hand once you get on your cell phone if you are having Teams audio issues. I apologize for that, Josh.

Katie, is that you with your hand raised?

DR. TAPP: I was just trying to help.

MS. LOPAS: Okay, all right, okay, I'm seeing one hand raised here from a member of the public, Matthew Williamson. Matthew, your microphone has been enabled, so you'll just need to unmute yourself and then please introduce yourself and go ahead and provide your comment.

MR. WILLIAMSON: Thank you very much, ma'am. My name is Matthew Williamson. I'm interested -- I understand this is an ACMUI review and not the Commission's review, but when we're talking about guidance being issued, since it's not under emerging technologies like the Part 1000, would the guidance, do we expect the guidance would be under something like a generic letter or an information notice? Can anybody comment?

DR. TAPP: Yes, this is Katie Tapp. When we do an emerging technology, a medical emerging technology review, and we find that there is some considerations we want to share with the regions, and our license reviewers, and with the states, we generally send those out through a memo to the regions as well as an STC or state and tribal letter, I believe, to the states.

We do post them then on our medical toolkit webpage and they're linked closely to the emerging technology licensing guidance documents there. So, they are publicly available, but the guidance is to the license reviewers and to the inspectors and then they can share with licensees as they deem appropriate.

So, that's generally where we would put

this type of guidance. If something is more universal or requires a generic communication, it could go there, but in this case, we're recommending a memo to our license reviewers and inspectors.

MR. WILLIAMSON: Thank you.

DR. TAPP: You're welcome.

MS. LOPAS: Okay, so one last call for comments on CivaDerm? All right, I am seeing none, Dr. Metter, so I will hand it back to you.

And Josh, just to let you know, I'm sending you an email right now about maybe potentially calling into the meeting if you're having issues with your Teams on your computer. I apologize.

CHAIR METTER: Well, thank you, Sarah. It looks like Josh did have some comments, and so, Chris, how could we go ahead and do this before we vote?

MR. EINBERG: Did he put his comments in the conversation or how do you know that he has comments?

CHAIR METTER: He was trying to speak and he was unmuted, but he had been enabled on our side.

MR. EINBERG: Okay, in that case, Dr. Metter, I would recommend that we table voting on this and just move to the next presentation, and then

we circle back on this presentation and do a vote when Josh can give his comments.

CHAIR METTER: Excellent suggestion. So, given that, let's move onto our next presentation. Can we have the next slides, please?

So, our next presenter is again Ms. Shober who has been working very, very hard for our committee as you can see, but she will present the subcommittee review of the draft revision of Regulatory Guide 8.39, Revision 2, release of patients administered radiopharmaceuticals draft report on the NRC staff's draft revision of this reg guide 8.39, Revision 2. So, Megan, it's all yours.

MEMBER SHOBER: Okay, thank you. Next slide, please. So, the Regulatory Guide 8.39 subcommittee is composed of Dr. Dilsizian, Dr. Jadvar, Mr. Mailman, Ms. Martin, and myself. Mike Sheetz has served as a consultant to the subcommittee since his resignation from the ACMUI in September, and Dr. Katie Tapp has been the NRC staff resource. Next slide, please.

This subcommittee was actually formed quite a long time ago in September of 2018 to review NRC staff's draft proposed revisions to Reg Guide 8.39. Reg Guide 8.39 was initially issued in April

of 1997 and then Revision 1 to this reg guide was issued in April of 2020.

So, the subcommittee began work again late this summer with the draft Revision 2, and this draft, it includes significant changes to the underlying dosimetry, the dosimetric modeling behind the release, patient release calculations and consideration. And, next slide, please.

Okay, you can continue to the next slide. So, the subcommittee did have some general comments about the Draft Phase 2 revision which we'll go through in greater detail.

One of the general comments we had is although the Phase 1 revision focused on changes to the patient instructions, when the Draft Phase 2 revision was released to the subcommittee for comment, we noticed that there were some changes to the patient instruction sections.

So, we have included some recommendations in this content area because we feel like the changes that were made in the patient instruction section negatively impacted the communication, so we do have a couple of comments in that.

And then just kind of as a general overarching comment, the subcommittee wants to

emphasize that it is important for the content of the guidance to be as clear as it can be and as easy to understand as it can be because this document is used by patients and the general public.

So, to the extent that the guidance can be, the complexity can be communicated in a way that's as accessible as possible, we feel like that is an important goal for this reg guide. Next slide, please.

So, to move into some of the more specific recommendations here, again Section 4.2 which dealt with the instructions, we recommend that these instructions be reordered to the original sequence, meaning how they were formatted for the Phase 1 revision.

We do want to emphasize up front and throughout that when patients are released, the primary source of radiation dose to other individuals is from external exposure to the patient, and so therefore, the most important precautions to take are measures which will reduce or avoid external radiation exposure from the patient, and this is most important in the first hours after release.

And to that end, although there are simple things that patients can do to limit the spread

of radioactive contamination, those measures should not detract from the external precautions because again, the external dose is the more significant cause of radiation dose to bystanders. Next slide, please.

So, just to get into some general comments about the changes to the dosimetric models, so with this revision to this reg guide, one of the main changes is that for isotopes with half-lives exceeding 24 hours, the underlying dosimetric model assumes an occupancy factor of one at one meter, and this is a significant conservatism compared to the previous modeling which used an occupancy factor of 0.25 at one meter.

So, the subcommittee's concern with this is that it significantly decreases the activity levels at which patient-specific calculations are required and also the activity levels at which instructions are required.

And for example, iodine-131 is one of the isotopes that would be subject to this increased occupancy factor and those activity levels at which patient-specific dose calculations are required are a factor of four lower than they were before.

And the subcommittee also wants to point

out that this Phase 2 draft revision is not consistent with the recordkeeping requirement in 10 CFR 35.2075(a) which requires retention of a patient release record in situations where you'd --

It's tied to the 0.25 occupancy factor at one meter, and so that recordkeeping requirement is not consistent with the draft in the proposed Phase 2 revision. Next slide, please.

The subcommittee recommends two sections be removed from this draft regulatory guide, Sections 1.3 and 3.3 which address release of a patient after a hold time.

Holding a patient after radiopharmaceutical administration to allow for decay is not practical and most of these patients would typically be released based on a dose rate at one meter or by a patient-specific calculation, and so requiring a fixed hold time is not really practical. Next slide, please.

As the subcommittee discussed the specific elements that went into the underlying dosimetric model, we believe that these modifying factors and the examples are overly complex and should be simplified.

So, being able to get data in order to

assign a value to the attenuation and geometric modifying factors, it requires a lot more information than is typically collected by nuclear medicine staff, and it requires licensees to predict unrealistically what is going to happen after the patient is released for quite a significant period of time.

So, the subcommittee recommends eliminating the attenuation and geometric modifying factors and looking for other places where certain pieces of that information can be simplified to better and more simply represent the conditions.

And then as far as the example calculations go, I really feel that to the extent that the reg guide can provide really good sample calculations, that's what licensees are going to want to be able to follow.

And so, the subcommittee also is recommending beefing up those example calculations, maybe providing a couple different hypothetical situations that licensees can really track through and follow how to apply this dosimetric modeling for the kinds of situations that they run into clinically. Next slide, please.

And then with regard to Section 6,

material separated from the patient, obviously this is the section that was added specifically with CivaDerm in mind. The subcommittee does not feel like this section should be included in Reg Guide 8.39.

There is disagreement about, with NRC's position about when or if dose limits in 10 CFR 20 apply versus when dose limits in 10 CFR 35 apply with the radioactive material that comes originally from a patient treatment.

And the other factor that goes into this with material separated from the patient is that the licensee can't reasonably predict when this type of situation may occur, and it would be very difficult to know how or if that exposure, like that source caused an exposure to a bystander.

So, at this point, the subcommittee doesn't see the value in that section, material separated from the patient, and we recommend that it be deleted. Next slide, please.

We had a couple of comments in Section 4.3 regarding the death of a patient following administration or implants, and this is just kind of a general recommendation to consider potential exposures from cremation of an individual who had

recently either received a permanent implant or radiopharmaceutical administration prior to death. Next slide, please.

And then just in general, we did provide a number of comments, specific comments with the hope of making the content clearer and easier to understand. Next slide, please.

All right, that concludes the presentation. Thank you.

CHAIR METTER: Thank you, Ms. Shober, for that very excellent presentation and very thorough review. Now I'd like to ask if there are any questions from the subcommittee or the ACMUI? Okay, seeing none and seeing no hands raised, I would like to go ahead and see if there are any comments from the NRC staff or questions?

Okay, also seeing none, at this time, let me go ahead and turn it over to Ms. Lopas for entertaining comments or questions from the public. Thank you.

MS. LOPAS: So, to make a comment -- yeah, I was muted. Thank you. I can't even follow my own directions, right?

So, to make a comment, please use the raise hand function. It's the little kind of hand

icon that you just click on at the top of your screen. After I have called on you, feel free to click that little hand icon again to lower your hand.

So, we're going to just go in the order that I'm seeing some raised hands. If you're on the phone and you need to make a comment, remember you'll press star, five.

So, I'm going to first enable Matthew Williamson's microphone. So, Matthew, just go ahead and unmute yourself. You have been enabled.

MR. WILLIAMSON: Fantastic, thank you. I just had a quick question about patient retention and how it was dissuaded waiting for biological decay or excretion. Can you clarify that?

So, obviously we don't want to release a patient if they're going to expose the public to more than 500 millirem, so how else would we do that if we don't hold the patient for decay or elimination?

MS. LOPAS: Okay, so unless I have a member of the ACMUI or Dr. Tapp who'd want to respond to that, that may be just a comment that we take back.

DR. TAPP: I would comment just that there is some supporting documents that have gone out and are being linked to the public website for the NRC's evaluation for the reg guide, so that might be

able to provide a more concrete answer to that question, but it -- and, yes, we will take that comment.

MR. SHEETZ: This is Mike Sheetz.

DR. TAPP: Go ahead, Mike.

MR. SHEETZ: Hi, there were some examples provided where the holding would be like for four hours or six hours, and so that was our concern, that really that's impractical to hold a patient the same day that you would administer the material.

And if you were going to do that, you would simply use the, you know, the exposure rate from the patient or patient-specific calculations to make the determination that it would be less than 500 millirems dose.

This was not intended to not be used for, you know, if you treated the patient as an inpatient and held them for one, or two, or three days, but then again, I think you would be using exposure rate measurements and not really trying to calculate a hold time based on decay or an assumed biological elimination. Thank you.

MS. LOPAS: Thank you, Mike. All right, the next commenter that we have up is Peter Crane. Peter, I am going to allow your microphone and you'll

just need to unmute yourself.

MR. CRANE: Okay, thank you, appreciate it. Okay, you wanted an introduction. My name is Peter Crane. I am the retired counsel for special projects at the Nuclear Regulatory Commission Office of General Counsel.

I've been involved in this issue for a long time. I've spoken on issues relating to radiation and thyroid cancer at conferences in Cambridge, England, Moscow, and Bonn, Germany.

I'm also a 48-year survivor of thyroid cancer. I've been treated multiple times with iodine-131, and I've been active in the Thyroid Cancer Survivors' Association for many years and have come in contact with hundreds, many hundreds of thyroid cancer patients in that time, and I have a pretty good idea of what is happening out in the real world.

I am troubled that not only is the regulatory guide deficient, but the comments of the ACMUI subcommittee would make it even more so. Mr. Williamson's comment, for example, is entirely on target.

There are places, responsible places where they say we will put you in a room for a while.

Wait until you have your first urination because so much of the material is eliminated in that time. I think it's Cleveland Clinic that will hold people for 23 hours because then they don't get -- insurance doesn't regard it as an overnight stay, but you get an awful lot of the iodine-131 out through the urine.

There is a major problem with the -- incidentally, I have submitted a statement for the record. You know, I could read it into the record, but I think that's probably unnecessary.

MS. LOPAS: Right, we will append that to the transcript.

MR. CRANE: Fine.

MS. LOPAS: So, Mr. Crane, it will be entirely public.

MR. CRANE: Fine. So, let me just speak. There is one good thing that's said in the regulatory guide where it says the NRC notes that the dose limits in 10 CFR Part 35 differ from many international regulatory requirements. Well, that's a fact.

That's been a fact for 25 years and there's never been an adequate justification for it from the staff or from the ACMUI. We are outliers in the world community, to a shocking extent to the world community.

I can tell you because I went to a meeting in Bonn of the International Atomic Energy Agency on Radiation Safety in Medicine, and the idea that patients were going with high doses of I-131 in their systems to hotels and that those hotel rooms were being cleaned up by workers, possibly pregnant, who had no idea that there was radiation in there, they were shocked.

And believe me, this happens. Do you know the Braidwood Hotel incident? I think that was 2007 when somebody set off -- a new employee in a nuclear power plant in Braidwood, Illinois set off the radiation monitors. Why? And they were puzzled. They were baffled because he was a new hire and he hadn't gone near the hot areas of the plant.

The answer was that he had slept in the Braidwood Motel, and the previous person to sleep in the Braidwood Motel was a patient who had just been released after outpatient I-131 treatment and had gone to the hotel, the motel because she didn't want to expose her family.

She left enough radiation in the room to contaminate the worker and set off the alarms in the nuclear power plant. That is, I mean, not only is that shocking and irresponsible, but, you know, it

can't simply be passed over in silence.

The crux of the matter is that in 1986, the NRC said, quite rightly, in rejecting the idea that you could base release on external dose to others, said that the dose was both from external and internal exposure and that trying to figure out the exposure to others, the external exposure, was too problematic. It was too tenuous because you just didn't know. Well, it's too hard to predict, and that certainly the ACMUI subcommittee agrees with that about, you know, predicting people's behavior. You can't do it. The question is whether you're going to err on the side of caution.

The NRC was right in that respect in 1986, and then in 1987, suddenly internal dose got eliminated. Why did it get eliminated? Because the NRC was placing primary reliance on a medical consultant named Myron Pollycove, who was a very nice guy.

He was an elderly doctor, but he was a leading member of the hormesis movement, and the hormesis movement which says that radiation is good for you, that even the effects of a dirty bomb could be beneficial to health if you didn't get exposed to the blast, that I-131 is not carcinogenic, and that

any effect, any health effect of a major nuclear accident, if any, would be positive.

Now, with all respect to the late Dr. Pollycove, those views are kooky, and time and again, the NRC relied on that. Well, time passes and the ICRP -- so, the international community got more and more concerned about internal dose after Chernobyl because of the 7,000 thyroid cancers in children exposed to fallout from Chernobyl, and a lot of that was internal dose of I-131.

So, ICRP, the International Commission on Radiation Protection, came out in 1997 with a report that highlighted the danger from internal dose to children, and the issue -- and commenters, expert commenters, people with doctorates and medical degrees will tell you, and the ICRP will tell you that the external dose is the greater risk to adults.

Internal dose is the greater threat to children, and children are far more radiation sensitive. You can find this in things written even by people who are major supporters of this rule. They somehow flip at some point on the subject as they justify this rule.

So, I had filed a petition in 2005 asking for revision of the current rule and the NRC denied

it, but they noted that, it noted that the ICRP had addressed it and it quite frankly confessed that the NRC had understated the risk to children from I-131.

So, they said but rulemaking would take lots of time. We will handle it in guidance, so indeed, they did handle it in guidance. They put out RIS 2008 something which said you should, licensees should seriously consider hospitalizing patients who have young children at home, and it acknowledged that it had failed to take adequate account of internal dose.

Well, that was sensible, but suddenly that's gone. That's gone from this reg guide and it's only going to be made worse by the subcommittee's recommendation which is let's talk about external dose. Let's not let considerations of internal dose interfere with the message that it's all about external dose. It isn't. And there are a couple of other things.

This is kind of angels dancing on a head of a pin. It bears no relation to what is happening in the real world. And you don't have to rely on me, and I'm sure you won't, for a description of what's happening in the real world.

You can look at a couple of ACMUI

members, including the former chairman, Leon Malamud, who said we whisk -- all patients are treated as outpatients at his hospital, which was Temple University in Philadelphia. We whisk them out the doors as quickly as possible. And he explained that the I-131 patient, he said, is an unwanted guest, and he gave three reasons.

One is that hospital staff is scared of them and doesn't want to deal with them. The second is that when you have an I-131 inpatient, you have to leave the adjoining rooms vacant because of the radiation coming through the walls, and the third is, and I quote, their wonderful insurance won't pay for it.

The other person in the same meeting was Dr. Douglas Eggli, a practitioner, and he said ever since the patient release rule went into effect, it's pulling teeth to get insurance authorization for less than 200 millicuries even when family situations require it.

MS. LOPAS: Mr. Crane, I'm going to have to ask you to wrap up because we do have another commenter behind you, but, you know, because I want to kind of get to the heart of this reg guide and --

MR. CRANE: Okay.

MS. LOPAS: You've been going on for -- I'm letting you go for about 13 minutes at this point, or about 12 minutes, so.

MR. CRANE: Okay, okay, well --

MS. LOPAS: So, if you could give me a closing, a nice closing statement? And I want to point out that this reg guide will go out for public comment as well, and, of course, we do have your entire five-page written statement that will appended to this transcript, so it will be publicly available with the transcript.

MR. CRANE: Right, I will just wrap up by saying I could give you examples of hospitals. All you have to do is call a hospital nuclear medicine department. They say yes, we send them out the door with 200 millicuries all the time.

Do you ever send them to hotels? Yes, some of our patients come from Alaska. I'm in Seattle and this was a Seattle hospital. They can't board a plane.

I said you know the NRC disapproves of that, strongly discourages that. That seems to have vanished from this reg guide. That was taken into account. You know the state of Washington says not to do it. That was taken into account.

That's what happens when you have non-binding guidance. It's ignored. They whisk them out the doors. That's the reality. All this fancy stuff about calculations, it doesn't happen. This is fantasy world and it's extremely unfortunate.

And there is something very wrong, I think, and I will wrap up with this, something very wrong if the maximum dose with which somebody can be let out of the hospital in most of the world, including the third world, is no higher than 15 millicuries, and in much of Europe, it's 12 millicuries or eight millicuries, and here, we're whisking them out the doors with 200 and 250 and sending them home to their small children with conflicting and minimal safety guidance.

It should be a disgrace to the NRC, a disgrace to the U.S. government that it evidently puts a lower priority on protecting children from the carcinogenic and other disease-causing effects of radiation than Bangladesh, South Africa, the Philippines, and innumerable other countries.

MS. LOPAS: All right, thank you, Mr. Crane. We appreciate your input, and like I said, your comment will be attached to the transcript.

Just a reminder, I saw somebody kind of

lower their hand. Maybe they want to raise it again. So, press the icon to raise your hand or star, five on your phone.

So, David Michael Schuster, I'm going to enable your mic and you will just have to unmute yourself in order to speak.

DR. SCHUSTER: Thank you. I should be unmuted now. Can you hear me?

MS. LOPAS: Yeah, we hear you.

DR. SCHUSTER: Perfect. I'm Dr. David Schuster and I am the Division Director of Nuclear Medicine at Emory University in Atlanta.

So, I'd like to take a contrary view to what has just been expressed. We interview all our patients, and also most of the academic centers I know, and many other centers also interview their patients. We do full consults a few weeks before. We know exactly what situation the patient is in.

We don't treat them if they're going to stay in a hotel, and in fact, there have been a few cases where we found out they were planning to stay in a hotel, and we withheld treatment until that occurred that they made alternative arrangements.

So, we give them very detailed instructions. We have a wonderful sheet occupancy

factor where we ask over 20 questions to come up with an occupancy factor made by our radiation safety office, and I think we have a very good handle.

And people and physicians are, obviously you're judging the patient like we do any other time for any other therapy, and this can be done safely and really without exposing the public to any undue exposure.

And in fact, our experience has been the patients come already with a lot of this knowledge and they even may be doing more than we asked them to. Now, I tell them, well, that's never a problem if you want to do more than we're asking you to, but, you know, this is what we do.

We go by how much they're given and how many days they have to do, you know, each particular activity, and if the NRC wanted to release, you know, model guidance for something like that, that would be fine, but, you know, to keep a patient for hours and hours, even 23 hours, it's not practical, especially, you know, in this time of where you need hospital beds and hospital facilities for others.

So, just to finish, there have been studies actually in other countries where they've done this kind of guidance and sent the patients out,

and not push the patients out the door, but sent the patients out with adequate adult instructions for adults and they've put radiation dosimeters both on the patient, on their families, etcetera, and in all cases, patients have not exposed the general public to, you know, high doses of radiation.

So, I think this could be done very well. This could be done very responsibly and to characterize it otherwise, I think, is inaccurate.

MS. LOPAS: All right, thank you so much, Dr. Schuster. The next comment we have will be from Jeffrey Brunette. Jeffrey, I'm going to allow your microphone and you'll just need to unmute yourself.

MR. BRUNETTE: There we go, got it.

MS. LOPAS: Yeah.

MR. BRUNETTE: So, I'm not going to comment on either of the last two. I just wanted to ask one question, and while I agree the patient-specific factors calculation methods, I agree with the point that they are overly complex, I was just wondering if the comment about, you know, understanding the patient's travel conditions and things like that.

And attenuation and modifying factors, while I think they could be simplified, there are

studies, and I don't have it in front of me, but I remember seeing Dr. Hertel talk about, I think it was a Hertel and Dewji study that was published a long time ago looking at this very point of patient travel, and it's kind of a grail of mine because I kind of did the same thing here at my facility prior to seeing this document.

So, you know, I just wanted to -- I was just curious if that was intended to say that, well, we shouldn't worry about travel, or if it was intended to be that you just want something simplified, and I'll leave it at that and mute.

MS. LOPAS: Okay, all right, thank you. We have the next comment from Steven Frank. Steven, I'm going to enable your microphone and you will need to unmute yourself, Steven, so you have to do a little action on your part. We got it.

DR. FRANK: Yes, thank you, Steven Frank from MD Anderson Cancer Center in Houston. I head our prostate brachytherapy program and I just want to make a couple of comments.

One, the factors of reducing to a quarter of the current limits can have significant implications on, you know, the release of patients. We've --

You know, a low-dose rate-brachytherapy is a standard of care treatment methodology for the treatment of prostate cancer and has been utilized for the last several decades in these patients as an outpatient procedure.

It's low cost, and if patients are going to try to meet these specific limits, it could require an additional stay at hospitals depending on the isotope, and that isotope will cause unnecessary expense to patients and a burden to the hospitals.

Furthermore, studies have been done on exposure limits to family members and have specifically calculated those exposure limits as less than a flight from New York to San Francisco.

So, I think studies have been done, and in characterizing these complex models, it probably would be worthwhile to have the societies like ASTRO, the American Society for Radiation Oncology, the American Brachytherapy Society, which I was the president of, and the AAPM, which is the American Association of Physicists in Medicine, to further weigh in on this new draft and recommendation. Thank you.

MS. LOPAS: Thank you, and this draft will go out for public comment. I believe that's

correct. Dr. Tapp, do you have an estimate of when this would go out for public comment?

DR. TAPP: I do not have an exact date today, but we will take the comments from the ACMUI, regions, and states and incorporate those into a document.

If all goes well, we are looking at later in the winter or early spring for public comment, but it is -- we want to consider how extensive the comments are from the ACMUI at this time and certainly push a little bit.

MS. LOPAS: Okay, thank you, Dr. Tapp. All right, so our next comment is from somebody on the phone, so I'm going to enable your microphone. Oh, the hand went down. So, I just saw a person on the phone press star, five. If you're on the phone, press star, five.

All right, I have another. Okay, so I'm going to grab this person on the phone here and then, Firas Mourtada, I see you next. I'll grab you next, but I think the phone person --

So, I'm allowing the microphone for a 206-987 number, and all you'll need to do now is press star, six, I believe, on your phone, and make sure your phone is actually, your physical phone is

unmuted, so let's see if you can speak. Oh, try it again. 206-987, are you there?

DR. ALDAPE: Hi, my name is Lisa Aldape. I'm commenting from Seattle Children's Hospital. I'm just following up with the previous comment. We also perform some front end I-131 MIBG therapies on our pediatric population.

We're one of a few, 15 hospitals across the nation that perform these therapies, and I just want the committee to be aware of the trickle-down effect of lowering the release criteria.

Currently, we're very careful. We have a great program and a very safe program, and if you do lower these criteria, the potential of keeping toddlers and young children and families in the hospital for almost double the amount of time they currently spend could happen.

I know you'll have a public comment to address this, but I do want the committee to be aware that these therapies are end of life salvage therapies per se and we save many, many kiddos, and although they're not very common, they're very important to treatment, and I just don't want to see --

It's not all just about I-131 thyroid

cancer. There's many other treatments that happen, that this lowering of this criteria could impact, so I just wanted the committee to be aware of that. Thank you.

MS. LOPAS: Thank you for that comment. All right, our next comment is going to be from Firas Mourtada. I apologize if I am mispronouncing that. So, Firas, I have enabled your microphone. You just need to unmute yourself now using Teams. And are you there, Firas? You just have to press the microphone button on Teams to unmute yourself. I cannot unmute you, but I have enabled your microphone.

Okay, maybe Firas is having issues with their microphone, so, Firas, I'm going to try one more thing for you. I'm going to maybe make you a presenter and see if that helps you with your microphone and let me know if that helped at all and you can try to unmute yourself that way. I'll give you one more chance and then we might have to move on.

DR. MOURTADA: Can you hear me? Can you hear me?

MS. LOPAS: Yes, now we can hear you, excellent, great.

DR. MOURTADA: My microphone was

unplugged. That explains it.

MS. LOPAS: Okay, all right.

DR. MOURTADA: Sorry about that. So, I'm Firas Mourtada. I'm a PhD Chief of Medical Physics at ChristianaCare at Newark, Delaware, as well as I am the ABS, the American Brachytherapy Society Chairman of the Board.

So, I have been looking at this with quiet interest. I looked at a couple of publications that actually came out really nice from Japan on the, you know, thousands of patients for process implantation for iodine-125 and palladium.

And I tried kind of to say okay, let me look at those data and see is this really realistic to go up to an occupancy factor of 1.0, and honestly, it's going to be very tricky because here is the idea.

If you're going to really measure at one meter around, where are you going to measure? Because the Japanese have reported different measurements if you do it supine, if you do it standing, the patient standing, sitting.

Is it lateral? Because, you know, as you know, low energy iodine is quite sensitive to where you make that measurement. So, you're going to have to also have high precision instrumentation.

You're no longer going to be able to really use a GM with, you know, the old needle where it goes -- you really have to have, you know, a Victoreen 450B with high precision. We're looking at 2.4 microsieverts per hour, for example, for iodine-125.

So, I cannot realize what I just saw today about the recommendations, that it's not practical for routine application to really do an occupancy factor of one, and the 0.25, probably that would remedy this, but this is my opinion. It's not really practical.

I do agree that we do need to protect the children and the public, but I don't think this is the right approach of looking at it. I hope we could have some common sense.

Brachytherapy is a highly valuable procedure. Look at the cost benefit compared to other modalities. It's wonderful and I would like to keep it for all my patients here in Delaware. Thank you for hearing me.

MS. LOPAS: All right, thank you, Dr. Mourtada. All right, next we're going to hear from Matthew Williamson. Matthew, I'm going to enable your mic and you'll just go ahead and unmute yourself.

MR. WILLIAMSON: I got it. Thank you. This is Matthew Williamson. I'd like to thank the committee for reviewing the draft reg guide. Thank you. Also, I just want to bring up -- I just want to comment, and it's been said by some folks on the line and it's been in this report as well.

Patient release, the thresholds for release and instruction are dose based, and the Commission recognizes that it's not about intent. It's not about therapy or diagnostic. It's about dose.

So, when we talk about these issues, it's about dose, and diagnostic radiopharmaceuticals also fall into these categories. You know, since NUREG-1492, tech-99m has been in the tables, and now with this draft, theranostics such as I-124 are also in there.

So, when we're talking about these issues, it's about dose and impacts, and we need to consider also the diagnostic agents. Thanks.

MS. LOPAS: Okay, thank you for that comment. All right, I don't see any other raised hands right now, so I'm going to do another call for raised hands.

So, hit the hand icon if you are logged

into the Teams meeting here and I'll enable your microphone, or if you're on your phone, press star, five on your phone. So, we'll do a last call for comments.

(No response.)

MS. LOPAS: Okay, I am not seeing any. I will keep an eye out for any other raised hands, but Dr. Metter, I think at this point, since I'm not seeing any raised hands from the public, I'm going to hand it back to you.

DR. TAPP: Sarah, this is Katie Tapp. Is it possible to check if Josh Mailman is back to be able to talk? I just wanted to make sure he has the ability.

MS. LOPAS: Yeah, oh, absolutely. Josh?

MR. EINBERG: He's here.

MS. LOPAS: Hi, Josh, okay.

CHAIR METTER: So, this is Darlene. I was going to go ahead and address Josh's comment when we go back to the CivaDerm. I think we should just complete the reg guide subcommittee --

MS. LOPAS: Sure.

CHAIR METTER: -- report at this time.

MS. LOPAS: I'm seeing one last raised hand here, Dr. Metter, so I'm going to take that.

So, Michael Welling, I'm going to enable your microphone and you'll need to just unmute yourself, then you can go ahead.

MR. WELLING: Thank you. My name is Mike Welling. I'm currently the Radiation Safety Officer at the University of Virginia. Prior to this, I was Director of the Virginia Radioactive Materials Program and I also spent six years on the Organization of Agreement States Board, including chairman for several years, performing quite a few presentations to the NRC regarding some of these issues, including I-131.

Being on both sides of the fence on this issue, I would like to go on record along with some other previous speakers saying that most licensees do a great job with regards to patient release. Obviously, there are some licensees that don't do due diligence and don't follow up as much as other licensees.

So, I would press instead of going this route and making this more restrictive, that all the Agreement States and the NRC do a better job during the inspections in enforcing the patient release criteria and the instructions that have to be done before we treat patients.

We shouldn't have to revise regulations or guidance documents when stuff is already out there to enforce for public health and safety. So, before we go this route, let's put the emphasis on the inspections, the burden to verify licensees are doing their proper due diligence. Thank you.

MS. LOPAS: Okay, thank you. Okay, I see no other hands raised, Dr. Metter, so again I'll pass it back to you.

CHAIR METTER: Thank you. Thank you, Ms. Lopas for very excellent entertainment of the comments from the committee, and particularly the public for their invaluable information that I know that the NRC staff will definitely consider in their final assessment.

So, at this time, I'd like to entertain any more final comments from the ACMUI or the staff. Okay, seeing none, do I have a motion to approve the subcommittee report on revision to Regulatory Guide 8.39? I'm sorry, who was that?

MS. LOPAS: That looks like that was Ms. Martin.

MEMBER MARTIN: Yes.

CHAIR METTER: Thank you, Ms. Martin, for that. Do I have a second for the motion?

MEMBER WOLKOV: Harvey Wolkov, second.

CHAIR METTER: Thank you, Dr. Wolkov. Do I have any discussion? All in favor of approving the subcommittee report on revision to Regulatory Guide 8.39, say aye?

(Chorus of aye.)

CHAIR METTER: Any abstentions or against the approval?

Hearing and seeing none, the subcommittee report is unanimously approved by the ACMUI.

So, let us go back and circle back to the previous subcommittee report on the CivaDerm, and I believe now that Mr. Mailman is unmuted and able to use his microphone, I turn it over to you for your comments. Thank you.

MEMBER MAILMAN: I don't believe I have a comment on this. I was raising my hand because I was having access issues.

CHAIR METTER: Okay, thank you, Mr. Mailman. Okay, given that, are there any final comments on the licensing guidance for the CivaDerm subcommittee from the ACMUI or NRC staff? Seeing none, do I have a motion to approve the licensing guidance for the CivaDerm subcommittee report?

MEMBER WOLKOV: Harvey Wolkov, I move

approval.

CHAIR METTER: Thank you, Dr. Wolkov. Do I have a second?

MEMBER O'HARA: Second, Mike O'Hara.

CHAIR METTER: Thank you, Dr. O'Hara. Do I have any discussion?

Seeing none, all in favor of approving the comments and the licensing guidance for the CivaDerm subcommittee report, say aye.

(Chorus of aye.)

CHAIR METTER: Any abstention or against this approval? Seeing or hearing none, the subcommittee report on the guidance for CivaDerm is approved, unanimously approved.

So, are there any other final comments from Mr. Einberg or any of the NRC staff for today?

MR. EINBERG: So, on behalf of the NRC, I wanted to thank the ACMUI and all of the members for all their diligent work on these three subcommittees, and I wanted to thank the NRC staff for their support of these subcommittees, and lastly, I wanted to thank the members of the public for their meaningful discussion on the topics.

As Dr. Tapp noted earlier, the Reg Guide 8.39 will be published in the spring time frame for

public comment. All of the comments will be considered and it's a very valuable input that we receive, not only from the ACMUI in making our guidance documents and our regulations, but we take the considerations of the members of the public into account as well, and so with that, I wanted to thank everybody and I'll turn it back to you, Dr. Metter.

CHAIR METTER: Thank you, Mr. Einberg. Do I have any final comments from the ACMUI or the NRC staff? I also would like to thank the subcommittee and the NRC staff for these excellent ACMUI subcommittee reports on the draft reports for the Alpha DaRT licensing guidance, the CivaDerm, and the Revision 2 for Regulatory Guide 8.39.

Today's discussions will definitely aid in the information that the NRC staff will use for their final or for their continuing assessment of these topics, to include the very valuable input from the public.

I think it was an excellent discussion and I look forward to further advancements of these topics. So, are there any final comments from the ACMUI or staff? So, hearing -- go ahead.

MR. EINBERG: Yeah, I was going to say none from the NRC.

CHAIR METTER: Thank you. So, at this time, hearing none, I wish you all a very safe and peaceful holiday season and all the best for the upcoming wonderful year of 2022. Thank you very much for your participation and the teleconference call is adjourned.

(Whereupon, the above-entitled matter went off the record at 3:39 p.m.)

**Meeting of the Advisory Committee on the Medical Uses of Isotopes**
**U.S. Nuclear Regulatory Commission**

**December 15, 2021**

**Statement of Peter Crane, NRC Counsel for Special Projects (retired)**

I am taking the opportunity to submit comments on the subject of the proposed revision to the NRC's Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material." I do so, however, without any illusions that it will make a difference to the outcome. Thirty years of experience with the NRC's handling of the patient release issue have taught me that on this subject, decisions are made in advance; hard questions go unanswered, if they are even asked; and public participation is little more than a charade.

There is one sentence in the draft Regulatory Guide under discussion today that deserves praise, however. Found on page 6, it reads as follows: "The NRC notes that the U.S. dose limits in 10 CFR Part 35 differ from many international regulatory requirements." This is a low-key way of saying that the United States is an outlier in the world radiation protection community. It would be more useful if it spelled out **how** our regulations fall short of international standards, and why the NRC considers this acceptable, but nevertheless, it is refreshing to find this statement of unvarnished truth in an otherwise problematic document.

The conflict with international requirements is not just in comparison to nations of the First World. The governments of Bangladesh, Macedonia, South Africa, and innumerable Third World countries all manage to conform to international standards. Does the fact that we do not do so mean that the United States cares less about the health and safety of its children than do these other nations? If caring is measured by our willingness to conform to what the best contemporary science says about the protection of children from radiation hazards, the answer is inescapable. To be sure, those other countries have the advantage that there, doctors and scientists make the rules governing medical uses of radiation, rather than bureaucrats in an agency susceptible to political pressure.

The 1997 Patient Release Rule represented the hijacking of the NRC's radiation protection standard – not without help from the inside -- by the advocates of the pseudoscientific "hormesis" theory, often summarized as "radiation is good for you." Parenthetically, the NRC quite recently rejected hormesis as a basis for regulation, denying a rulemaking petition that asked that everyone, specifically including babies, fetuses, and pregnant women, be allowed to receive 10 rems of radiation per year, on the grounds that such a dose could not be harmful and might be hormetic. That is 20 times the current limit, and 100 times the limit recommended by international and national organizations. The petition also asked for the abolition of the ALARA principle, by which licensees are required to keep radiation exposures "as low as reasonably achievable."

That petition, which the Commission quite rightly rejected, came from the selfsame individual who proposed the Patient Release Rule some 30 years ago. Doesn't that suggest that it might be worth taking a close look at that rule as well?

Until 1997, the NRC's regulations had been in full compliance with international standards and practice. The rule change of that year, by abolishing the 30-millicurie rule, and allowing release to be based on the estimated dose received by others, had immediate results. Insurance companies stopped paying for inpatient treatment, and hospitals, with few exceptions, stopped offering it.

Only 11 years earlier, in 1986, the NRC had explained cogently why the 30-millicurie rule was essential: to protect against both external **and internal** radiation dose. It also explained that using estimated dose to others as a standard was not practicable, because of the uncertainty of the assumptions involved.

What was wrong with that analysis? What if anything had changed in the intervening years, to make the NRC reverse itself? The NRC never said. It simply declared, in a purported analysis given the number NUREG-1492, that internal dose did not need to be taken into account, citing its medical expert, the late Dr. Myron Pollycove. It is worth noting that Dr. Pollycove also believed, among other things, that I-131 was not carcinogenic, and that any health effects of a major nuclear accident would be **beneficial**. So significant a departure from longstanding NRC principles might be thought to require a more solid basis in science than "Dr. Pollycove said so," but for the authors of NUREG-1492 and the NRC, it was good enough.

Agencies can, of course, change their policies. But their discretion to do so is not unlimited. As the Supreme Court wrote in *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009): "To be sure, the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position. An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books. See *United States v. Nixon*, 418 U. S. 683, 696 (1974). And of course the agency must show that there are good reasons for the new policy."

That did not happen here. The previous policy, and the reasons articulated for it, went down what George Orwell referred to in *1984* as the "Memory Hole," as though they had never existed.

In 2007, the NRC was given a hair-raising account of actual practice under the new Patient Release Rule. It showed that the individualized analysis of patients and their living situations envisioned by the rule was not occurring. Instead, the hospital being described had made a blanket decision to treat everyone as an outpatient, for three reasons: hospital staff was afraid of radioactive inpatients; the rooms adjoining theirs had to be left vacant, owing to radiation penetrating the walls; and "their wonderful insurance won't pay for it."

That account did not come from me, or from some other thyroid cancer patient, but from a practitioner, the then Chairman of the ACMUI, Dr. Leon Malmud. Time and again, over

the intervening years, I have quoted his memorable words: "All patients are discharged upon treatment. We whisk them out the doors as fast as possible." Neither the ACMUI nor the NRC staff has ever addressed the question of whether that was an accurate portrayal of current practice – which of course it was – or mentioned it at all. It is as though someone had made a rude noise at a dinner party, which everyone then pretends not to have heard.

Years ago, it was pointed out by a courageous NRC staff member that the 1997 rule had outsourced the radiation safety of the public to the patients, whereas previously it had been the responsibility of the licensee, which could be penalized if it fell short. Now, protection was only as good as the conscience of the individual I-131 patient, who was beyond the NRC's jurisdiction. The response of the ACMUI subcommittee was: "Well-informed patients are self-motivated and sensitive to the fact that they are radioactive for a period of time, excreting radioactivity, and will typically do as much as possible to reduce potential exposures to family, caregivers, and other members of the general public." No source was offered, or could have been offered, for this extraordinary statement, which appears to have been plucked out of the air. Covid-19 patients don't seem to be universally altruistic about protecting others from harm. What reason is there to think that thyroid cancer patients are so much nobler than Covid patients?

Years ago, after I raised the issue of radioactive patients sent to hotels, Dr. Pat Zanzonico of this Committee performed an analysis that purported to show that no hotel worker or hotel guest could get a significant radiation dose from an I-131 patient. I pointed out, in an ACMUI meeting, that he had not considered internal dose from the patient's urine. He disagreed, arguing that he **had** looked at urine – the urine left in the patient's sheets. In a subsequent ACMUI meeting, I asked why had he not also looked at the urine left in and around the toilet. To that, the then Chairman of the ACMUI replied, "We're not going to debate that here, Mr. Crane."

As far as I was concerned, however, this wasn't a matter of debating, I was asking a reasonable and germane question of fact, which like so many others, has never been answered.

If the NRC were the agency I wish it were, the avoidance of hard questions and the proffer of absurd rationalizations would not be possible, because there would be Commissioners **demanding** answers. The same could be said for Congressional oversight.

The sad reality is that we have reached a point where there is an almost complete disconnect between what is happening on paper, which is what this Regulatory Guide is about, and what is happening in practice. It used to be said, in the former Soviet bloc, "They pretend to pay us, and we pretend to work." Today it might be said, "The NRC pretends to regulate nuclear medicine and the licensees pretend to comply." The licensees who were "whisking them out the doors as quickly as possible" in 2007 are still doing so today, and this will continue so as long as the NRC's regulations make that possible. This Regulatory Guide is advisory, non-binding, and unenforceable, and it would be naive to expect that licensees'

behavior, which is driven primarily by considerations of cost, will be changed by it. Only a rule change will accomplish that, and if the NRC staff, the ACMUI, and the Commission think otherwise, they are fooling themselves.

Importantly, however, there are exceptions: licensees that do the right thing, just **because** it is the right thing, without regard to cost. Washington Hospital Center is one of these. It continues to hospitalize all patients receiving 30 millicuries or more of I-131, just as if the Patient Release Rule had never been put in place. In an ideal world, Chairmen and Commissioners would hold an open fact-finding meeting, and invite, among others, Dr. Ken Burman and Dr. Doug Van Nostrand of Washington Hospital Center to explain the basis for their approach, as well as doctors who see no need to hospitalize patients in such situations.

It may be asked why I bother to submit comments, if I see so little likelihood of their making a difference. There are several reasons. The first is that I am writing in part for the record: for the day that the media, or academia, or the Congress, take a hard look at how the regulation of radioactive iodine treatments went off the rails at the NRC, and then was allowed to stay that way. Perhaps some scholar with an interest in the phenomenon of regulatory capture will decide to write a doctoral thesis or a book on the NRC and the patient release issue.

A hard look will reveal that in the area of patient release, the NRC abandoned reputable mainstream science, as understood the world over, to dwell in a kind of parallel scientific universe, founded in fantasy and quackery. In that alternative universe, internal doses of I-131 are not a hazard, patients can safely go to hotels with 200 millicuries of I-131 in their systems, an infant or a fetus can legally receive up to 500 millirems of external radiation, and patients are all so considerate of their fellow men, women, and children that they can be relied on to do the right thing, making hospitalization unnecessary. That bears no more relation to reality than the notion that radiation from a dirty bomb can boost your health.

First and foremost, however, the patient release issue is for me a human issue, defined by the patients I know who have been denied inpatient treatment in situations that demanded it. A few I have been able to help, but most have no choice but to take what they are offered, even if that means returning to a small dwelling with young children and only one bathroom. I think that is wrong. I think it is also wrong that a pregnant hotel housekeeper can be cleaning the bathroom of a high-dose patient, unaware of the radiation hazard. So long as those wrongs continue to occur, while the NRC studiously looks the other way, I would feel complicit if I failed to speak up.

For those who want to preserve the current rule, the easiest out, of course, is to say that I am inventing all of this. That was the approach taken, for example, by the NRC lawyer who assured the judges of the Ninth Circuit Court of Appeals that **no** radioactive patients were going to hotels – while at the same time that the NRC staff was estimating, in an internal document, that five to ten percent of patients went to hotels after treatment, and promising to

issue safety guidance on the subject. That guidance appeared in 2011 in the form of a Regulatory Issue Summary, in which licensees were told that the NRC "strongly discouraged" releasing I-131 patients to hotels, but sometime after that, it too vanished down the Memory Hole, without explanation.

Let me again quote a member of this Advisory Committee, in the hope that even if my words are disbelieved, his will be given credence. Here is Dr. Douglas Eggli, of the Milton S. Hershey Medical Center at Penn State, and the Nuclear Medicine Specialist of the ACMUI, speaking in a Committee meeting in October 2007: "We can't get a preceptor to admit most patients to the hospital any more from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries, the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it,** it's fighting tooth and nail with the insurance companies....."

It is to Dr. Eggli's great credit that he was **willing** to fight tooth and nail for the safety of his patients and their families. But not all doctors are that conscientious, and if their facilities lack the rooms to house I-131 inpatients, it is hardly likely that they will spend time and energy proving to the insurance company that inpatient treatment is necessary.

**Conclusion**

In my comments on the 2019 draft of this Regulatory Guide, I wrote that the "central, continuing problems with the NRC Patient Release Rule go unaddressed and untouched." They were: "(1) that patient release is based upon calculated external dose, on the assumption that internal dose is inconsequential; (2) that the NRC allows radiation doses to family members and the public that are five times what national and international standards call for; (3) that non-binding guidance has proved ineffective in correcting the inadequacies in current protection; (4) that the rule has been interpreted to allow newly treated patients to go to hotels, where they contaminate the rooms they stay in and the linens they sleep on; (5) that the NRC has outsourced the protection of the public from licensees, where it belongs, to the conscience of the individual patient, who may or may not be informed and altruistic; and (6) that in practice, the rule allows insurance companies, who look only at the bottom line, to dictate whether patients and their families receive adequate radiation protection."

That statement is equally true of the latest iteration. It's very difficult to make the NRC discuss something it doesn't want to discuss.

Finally, I mentioned earlier this Committee's finding that radioactive patients "will typically do as much as possible to reduce potential exposures to family, caregivers, and other members of the general public." Why should anyone believe that, when the same cannot be said for the NRC itself?